

PREDICTIVE FACTORS OF RESPONSE TO A SINGLE INJECTION OF MANNITOL-MODIFIED CROSS-LINKED HYALURONIC ACID (HANOX-M-XL) IN PATIENTS WITH TRAPEZIOMETACARPAL OSTEOARTHRITIS.

RESULTS OF A MULTICENTRE PROSPECTIVE OPEN-LABEL PILOT STUDY (INSTINCT TRIAL)

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Background

Viscosupplementation is likely effective to alleviate pain and improve function in patients suffering from rhizarthrosis. However, no study has been focused on the predictors of the treatment efficacy.

Objectives

Identify predictive factors of success or failure, 3 months after a single intra-articular injection of a mannitol-modified hyaluronic acid (HA) viscosupplement in patients suffering from trapeziometacarpal (TMC) osteoarthritis (OA).

Patients and methods-1

3-month prospective multicentre open-label trial

Investigators: rheumatologists or orthopedic surgeons, specialized in hand OA.

Main inclusion criteria: symptomatic TMC OA, of Dell grade 1 to 4 on plain radiographs (Kapandji incidence), not adequately relieved by analgesics or NSAIDs and/or by the use of a thumb orthotics.

Main exclusion criteria: inflammatory arthritis, trapezo-scaphoidal OA, patients who previously received intraarticular injections with corticosteroids into the target thumb.

Patients and methods-2

The study received the French health authorities approval and was conducted in accordance with the Ethical Standards of the Declaration of Helsinki.

Treatment under study: a single injection of 0.6 to 1 ml of **HANOX-M-XL**, a viscosupplement made of a cross-linked HA of high molecular weight (16 mg/ml), from biofermentative origin, combined with mannitol (35 mg/ml).

All injections were performed under fluoroscopic or ultrasound guidance.

Primary endpoint: variation between injection (D0) and day 90 (D90) of the thumb pain measured on 11 point-Likert scale (0 to 10).

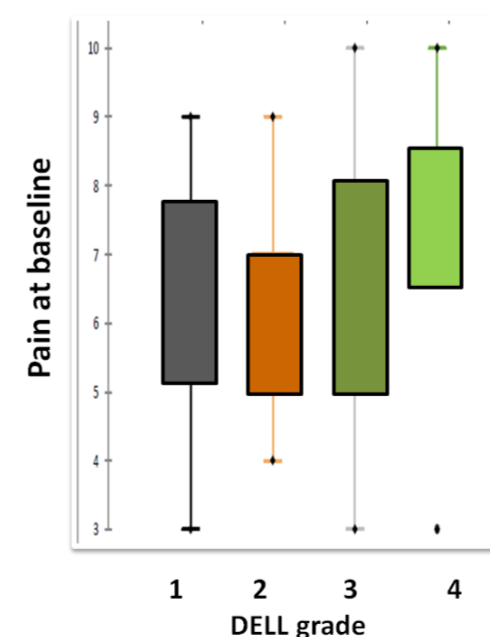
Secondary endpoints: patient's self-assessment of efficacy (0 to 3), decrease in the use of analgesics, safety and local tolerability. Predictive factors of pain decrease were studied in univariate and multivariate analysis. All statistical tests were carried out two tailed at the 5% level of significance.

Results-1

122 patients (76% females, mean age: 60, mean disease duration: 36 months) were included and 120 (98%) were assessed at Month 3.

Dell grade: 1 (23%), 2 (36.8%), 3 (36.8%) and 4 (3.5%).

At baseline, the average (SD) pain level was 6.5 ± 1.6 without significant difference between Dell groups ($p = 0.21$).

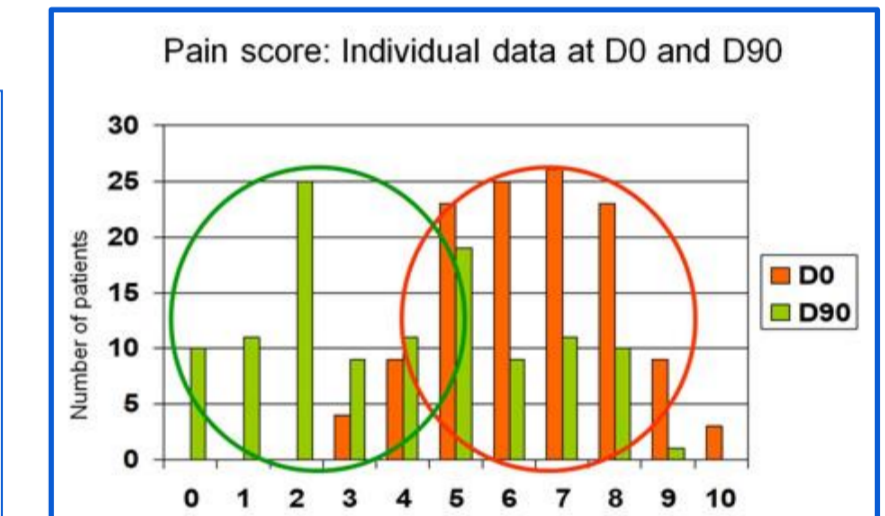
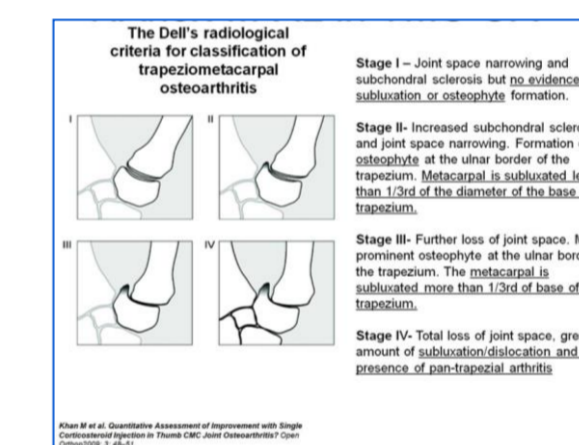
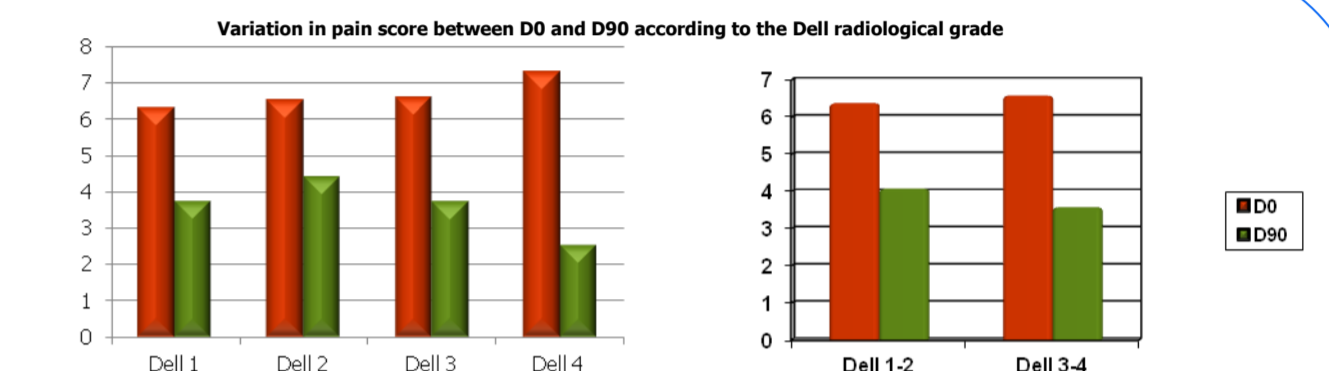
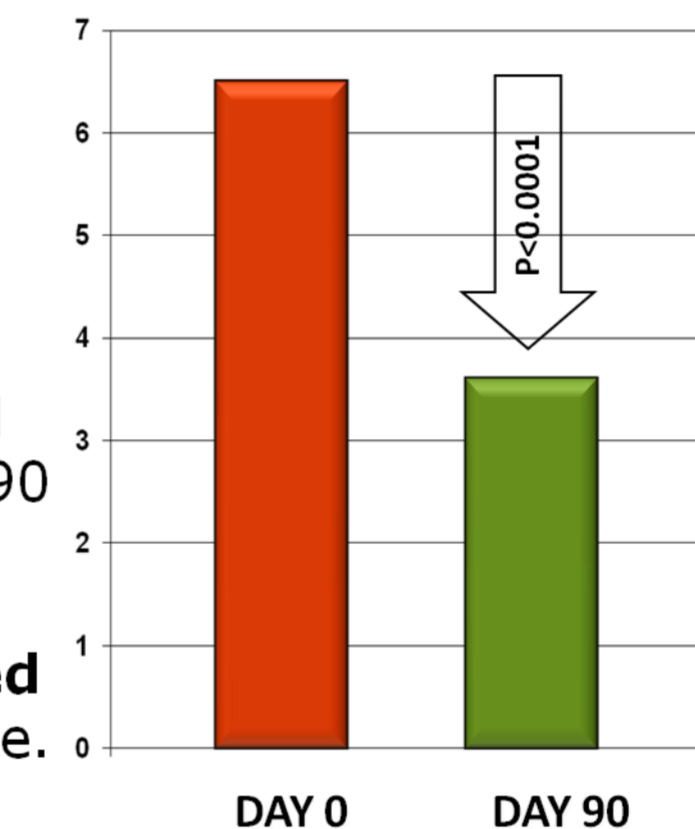


Results-2

Between D0 and D90, pain on VAS (SD) decreased from **6.5 (1.6)** to **3.6 (2.5)** ($p < 0.0001$)

57.5% of patients reached the **PASS threshold** at D90 (versus **10.6%** at D0)

51% of patients **decreased NSAIDs/analgesics** intake.



Results-3

In univariate analysis, the clinical response was significantly worse in patients taking NSAIDs at baseline ($p = 0.012$).

In multivariate analysis no predictor of response was identified.

There was no safety issue. All AEs (11%) were transient increase of pain during or following HA administration and resolved without sequel within 1 to 7 days.

Conclusion

This study, concerning the largest cohort of patients treated with viscosupplementation in TMC OA, suggests that **a single course of HANOX-M-XL injection is effective in relieving pain without safety concern.**

Patients with the more advanced stages of OA seem to benefit the treatment as much as those with less advanced OA.